ATTACHMENT A

Questions and Answers Related to Ingredients of Public Health Concern

I. Questions and Answers Directly Related to FSIS Notice 45-05, "Verification of Activities Related to An Establishment's Controls for the Use of Ingredients of Public Health Concern"

1. Question: "FSIS Notice 45-05 mentions allergens. Congress has identified the 8 major food allergens in the Food Allergens Labeling and Consumer Protection Act (FALCPA). What does the FALCPA require and why hasn't FSIS adopted it?

Answer: The FALCPA amended the FDCA and directed FDA to implement certain labeling requirements (among other provisions) for the "big-8" allergens that apply to foods under FDA's jurisdiction. For example, under the law, any ingredient with a common or usual name that does not reflect that it was from a "big-8" source, e.g., sodium caseinate, would need to be labeled to reflect the source, e.g., sodium caseinate (milk). However, the FALCPA did not amend the FMIA, PPIA, or EPIA, or the implementing regulations and policies for meat, poultry and egg products. Therefore, FSIS is in the process of developing a proposed rule to provide for the same type of "plain English" labeling as provided for in the FALCPA for meat, poultry, and egg products under the jurisdiction of FSIS. Until the rulemaking is completed, FSIS will permit, but not require, voluntary allergens labeling in concert with the 2002 Allergens Voluntary Labeling Statements policy at http://www.fsis.usda.gov/OPPDE/larc/Ingredients/Allergens.htm .

2. Question: How does FSIS Notice 45-05 relate to the FALCPA and why does it identify ingredients, such as monosodium glutamate (MSG), sulfites, lactose, and Yellow 5, that are not food allergens?"

Answer: As noted above, the intent of FSIS Notice 45-05 is not linked to the FALCPA. As the Notice explains, FSIS recognized that there has been a sustained number of product recalls due to the non-declaration of ingredients of public health concern. The Agency has long maintained the need for adequate in-plant ingredient controls and appropriate labeling of all ingredients by common or usual name. Food allergens are of particular health concern; however, the Agency is equally concerned about all foods or food ingredients that may cause adverse health effects in sensitive individuals. That is why the examples of sulfites, lactose, and Yellow 5 were provided; they are examples of ingredients to which consumers have reported having adverse effects.

3. Question: "The Notice refers to ingredients that may cause reactions in sensitive individuals. One example, lactose, is a GRAS substance. Why would GRAS ingredients be of public health concern?"

Answer: All ingredients used to manufacture meat, poultry, and egg products are required to be safe and suitable for use in the production of meat, poultry, and egg products. The designation of certain substances as GRAS relates to a determination that the ingredient is safe for human consumption. However, it is not the safety of the substance itself that is the problem. What poses concern to the Agency is the inadvertent addition of ingredients that have been reported to cause adverse health effects in sensitive individuals to the product, and the consequent non-declaration of those ingredients. Therefore, establishments should consider in their hazard analysis the necessary in-plant controls to ensure the appropriate control of ingredients, particularly those that cause food sensitivities, even if the ingredients are GRAS.

4. Question: "The Notice states that inspection personnel should issue a noncompliance record (NR) when the establishment has not properly disclosed on the product label that the product's formulation includes the use of an ingredient that is known to cause an adverse reaction. What is meant by the term "properly disclose" in paragraph III. B, in the Notice?"

Answer: "Properly disclose" refers to the declaration of an ingredient by common or usual name in the ingredients statement on labeling.

5. Question: "Does FSIS Notice 45-05 address cross-contamination or is it limited to proper labeling of intentionally added ingredients?"

Answer: The Notice is intended to address the need to properly control the use of ingredients that can cause adverse reactions. HACCP systems are documented in the literature as means of considering the potential hazard of failing to appropriately control ingredient addition (see Deibel, et al., 1997. A Comprehensive Approach to Reducing the Risk of Allergens in Foods. *J. of Food Protection* 60(4): 436-441)). SSOPs are intended to address the issue, as well. According to the literature, "allergen-prevention plans" involve mapping ingredients through flow diagrams of the processing system because one of the major concerns regarding allergens is cross-contamination. While cross-contamination is a possible result of the inappropriate use of an ingredient of public health concern, the main purpose of the notice is to remind inspection personnel of the need to verify that plants have considered the appropriate controls necessary for the use of ingredients in their HACCP system and that all ingredients are appropriately declared in labeling.

6. Question: "FSIS Notice 45-05 states that 'the flow chart and hazard analysis identify which products may contain ingredients that cause adverse reactions'. Current HACCP regulations don't require establishments to include product names in their flow charts. Is this in fact what the Agency intended?"

Answer: According to 9 CFR 417.2(a)(2), a flow chart describing the steps of each process and product flow in the establishment shall be prepared, and the intended use or consumers of the finished product shall be identified. The purpose of a flow chart is to ensure that an establishment has adequately addressed the consideration of hazards that may occur. With regard to ingredients of public health concern, FSIS does not require a flow chart for specific products or ingredients of public health concern, and the flow chart do not need to include "product names." It may refer to product groupings, categories (e.g., ready-to-eat meals), or product lines (e.g., frozen dinners). Further, the flow chart does not need to reference the specific names of ingredients and may refer to them as a general category, e.g., ingredients that cause adverse health effects.

Using the flow chart and hazard analysis, FSIS expects that establishments will employ the appropriate food safety systems procedures (i.e., HACCP plans, SSOPs, or other prerequisite programs) for ensuring that ingredient addition appropriately matches the formulation of the product, and that only ingredients in the product formulation are used.

7. Question: "Consumers have reported adverse reactions to ingredients that have been classified as sources of food intolerances, such as sulfites, lactose, and Yellow 5. The scientific evidence about these ingredients has not been debated. However, there seems to be a debate over whether MSG causes adverse health effects in individuals. Should it be included as an example in FSIS Notice 45-05?"

Answer: Given the available evidence, FSIS recognizes that there is not a basis to require that MSG be treated as presenting a public health concern. Nonetheless, given the significant consumer concern about this ingredient, FSIS urges companies to ensure that its use is properly declared in labeling. This is why FSIS included it as one of the examples in FSIS Notice 45-05.

8. Question: "What training and guidance is FSIS providing to inspection personnel on reviewing a Hazard Analysis and Critical Control (HACCP) plan with regard to ingredients of public health concern?"

Answer: The verification procedures in the FSIS Notice 45-05 are routine procedures that inspection personnel have been performing for years. Current training efforts in FSIS cover inspection verification activities. Additional guidance on the intent of FSIS Notice 45-05 is being provided through the questions and answers in this document. The Agency's concern is with the inappropriate addition and consequent non-declaration of ingredients, especially ingredients that have been reported to cause adverse health effects. FSIS Notice 45-05 does not require inspectors to identify the ingredients that may cause adverse reactions. The Notice reiterates that inspection personnel need to continue to verify that *establishments* have taken the appropriate steps to ensure that they have considered the necessary in-plant controls (e.g., Sanitation Standard Operating Procedures (SSOPs), HACCP plan, or prerequisite program) to prevent the inappropriate addition of ingredients and that all ingredients (with the exception of spices and flavorings defined in 9 CFR 317.2 (f)(1)(i) and 381.119 (c)) are labeled.

9. Question: "What is meant by the term 'chemical composition' in the description of the causes of adverse reactions to ingredients in the Notice?"

Answer: Within the context of the discussion in the Notice, the term "chemical composition" is described in the scientific literature as involving an adverse reaction to a substance or one of the elements of which the substance is composed. That is what is meant by the term "chemical composition" in the Notice.

10. Question: "The Notice states that the inspector will verify that establishments are ensuring that all ingredients are declared on labeling. How should establishments label their product when an incoming ingredient, e.g., a spice mixture, contains a 'may contain' statement on its labeling?"

Answer: All ingredients listed on the labeling of incoming food and food ingredients (e.g., a seasoning mix produced under FDA's jurisdiction) need to be carried through to the labeling of the meat or poultry product in which they are used as ingredients. This includes ingredients that are listed on the incoming foods or food ingredients as part of a "may contain" statement (e.g., "pork sausage {pork, water, seasoning (salt, pepper, hydrolyzed soy protein may contain: wheat, milk), sugar})."

11. Question: "Can an establishment use a prerequisite program as a control in the use and labeling of ingredients of public health concern?"

Answer: Yes, FSIS has stated publicly that prerequisite programs, such as SSOPs, are a way to address the control of ingredients to prevent cross contamination.

12. Question: "In regard to ingredients of public health concern, is the Agency concerned about commingling of mixed grain ingredients at the time of milling that may contain major food allergens, e.g., wheat ? Can FSIS help resolve this issue?"

Answer: The Grain Inspection, Packers and Stockyards Administration (GIPSA) has jurisdiction over the inspection and marketing of grains and is aware of the issue for consideration.

13. Question: "Under part III, B, 3, as long as the product is appropriately labeled with all ingredients, does the establishment have to include a statement that it contains certain allergenic components and indicate those again?"

Answer: No. The establishment is not required to add additional labeling terminology, e.g., that the product contains allergenic ingredients. FSIS regulations require only that all ingredients be declared by common or usual name in the ingredients statement.

14. Question: "Why does an Enforcement Investigations and Analysis Officer (EIAO) have to conduct a comprehensive food safety assessment (FSA) if the establishment addresses the control of ingredients in a prerequisite program?"

Answer: The EIAOs have the responsibility to assess the design of prerequisite programs to ensure that their use supports the decisions made in the hazard analysis.

15. Question: "On page two, Section 3, B (1, 2,& 3), do we have to fail all three items to receive an NR or just one of them?"

Answer: An NR can be issued if just one of the three listed examples has not been met by the establishment

16. Question: "If a plant does not follow the procedures outlined in its HACCP plan, as to how it handles allergens, is this a basis for an NR?"

Answer: If an establishment has incorporated procedures into the HACCP, SSOP, or other prerequisite program to address the hazards identified in the hazard analysis, then those procedures must be implemented to ensure that the identified hazard is controlled. If the procedures are not followed, inspection program personnel are to take action as described in FSIS Directive 5000.1, Revision 1.

17. Question: "I am a Federal Establishment that does not use ingredients. We simply process product (e.g., cut steaks and slice smoked hams) into retail packages. How do we comply with FSIS Notice 45-05?"

Answer: If a plant processes single ingredient products (e.g., beef steaks) or is receiving product that contains ingredients (e.g., smoked hams) and all they do is slice them, then ingredient controls are not necessary. However, the establishment needs to ensure that all ingredients declared on the incoming product carried through to the meat or poultry product label.

18. Question: "Our establishment makes multiple types of burritos. We make one burrito with a tortilla that contains yellow #5. Later, we make several burritos that do not contain yellow #5 in the tortilla. Will we need to sanitize our production line between runs to ensure no trace amounts of yellow #5 are present?"

Answer: The establishment should ensure that its SSOPs are adequate. An establishment should be able to show that: (1) it has considered the hazard and has documented the controls it designed to avoid the hazard if it exists (e.g., cross-contamination because of inadequate cleaning), or (2) that the hazard doesn't exist based on evidence that they have documented. Poorly cleaned equipment will usually shows signs of food product residue, not residue of just "protein" or a residue of one particular ingredient, e.g., Yellow #5 or sulfites. In this case, unless the inspector actually sees a sanitation problem, they should not automatically expect that residue is present that presents a breach in good SSOPs.

19. Question: "Our establishment makes several kinds of fully cooked chicken patty nuggets. Our cooking process involves deep-fat frying in soybean oil (which, like most oils in food, is refined). One line of breaded chicken nugget product contains soy protein while another does not. Both products are deep fried in the same fryer and we have never seen the need to dispose of the oil between production runs of these products. Is there a potential problem with cross-contamination?"

Answer: According to information available on the Institute of Shortening and Edible Oils website, foods may be cooked in edible oils resulting in traces of the allergenic proteins being left behind in the oil. Establishments that use the same oil as a cooking medium for a variety of products should consider the potential hazard to food-allergic consumers that the shared use poses in their SSOP or other pre-requisite programs and hazard analysis.

20. Question: "I am a small processor and do not have the ability to dispose of the vegetable oil that I use as a cooking medium (for heat setting batter and for frying breaded meat and poultry products). What might be the alternatives for me to deal with the potential for proteins from one breading being left in the oil from cooking differently formulated products; can I just label the products as "may contain (name the protein)?"

Answer: Whether the shared use of oil as a cooking medium poses a potential source of an adverse reaction by sensitive individuals is something that the establishment needs to consider. "May contain" labeling should not be the immediate response. If the processor cannot dispose of the oil between runs of differently formulated products, the processor should consider whether filtering or diluting the oil is possible to limit the likelihood of the hazard that shared use may present. If the establishment chooses to filter or dilute the oil and documents this as a way that it addresses the hazard, FSIS would likely accept this approach. However, FSIS would not be agreeing that the levels of allergenic substances that may still be present in the treated cooking oil represent an acceptable threshold; only FDA can determine that. If the establishment believes that the levels of allergenic substances cannot be reasonably or practicably reduced in managing the use of their oil cooking medium, they should explain why a "may contain" approach to labeling is warranted with the submission of such labeling for approval to FSIS. The policy on "may contain" that relates to allergens was considered in the FSIS guidance on the web at: http://www.fsis.usda.gov/OPPDE/larc/Ingredients/Allergens.htm.

II. Questions and Answers Concerning Ingredients of Public Health Concern

1. Question: "I have transferred my ingredient supplier's ingredients statement into my meat product label; however, when reviewing the manufacturer's product specification documents, the supplier states that the product "may contain soy, milk." The reference to soy/milk is not on the incoming ingredient mix label, so what should I declare on my label?"

Answer: The general rule is that the ingredients on the labels of foods and food ingredients prepared under FDA jurisdiction are transferred to the labels of meat, poultry, and egg products. Therefore, if the labeling of the purchased FDA product, including the ingredients statement, does not include the "may contain soy, milk" statement, it would not be transferred to the meat, poultry, or egg product label. However, it would be prudent for the meat, poultry, or egg product manufacturer to seek clarification from their ingredient supplier about the meaning of the "may contain" statement that appears in the product specification document, but not on product labeling, and to consider the need to include the information in their hazard analysis.

2. **Question:** "Do establishments need to label soy lecithin or wheat starch which has been used by the establishment as releasing agents on conveyor belts and packaging materials for a documented period of time?"

Answer: Yes, these ingredients have always been required to be declared because FSIS is not aware of any threshold below which ingredients containing protein do not need to be declared. Any substance that comes into contact with or is used to formulate a meat or poultry product is considered an ingredient that requires labeling unless FSIS has determined that the use of a substance meets the Food and Drug Administration's (FDA) definition of an incidental additive or processing aid in Title 21 of the Code of Federal Regulations (21 CFR), Section 101.100 (a)(3). As expressed in the 1995 ingredient labeling policy guidance cited previously, FSIS does not consider ingredients (e.g., substances containing protein) that may cause adverse reactions in certain consumers to be exempt from labeling as an incidental additive or processing aid because there are no established thresholds below which FDA has concluded that food sensitivities cease to exist regarding protein-containing ingredients. Furthermore, there are no regulations for meat and poultry establishments to "self determine" that the use of an ingredient is a processing aid.

3. **Question:** "If an establishment has been producing a product using soy lecithin or wheat starch as a release agent, which have not been declared on labeling, will it be able to continue using the labeling?"

Answer: An establishment may continue to use soy lecithin and wheat starch as release agents without submitting to FSIS for temporary approval to use up current label stock if the following conditions apply: The establishment (1) documents as part of the labeling record the current volume of label stock that does not reflect these ingredients for which a temporary approval is needed; (2) states on the label application or as part of the labeling record (which must be maintained by the establishment according to) that the purpose of use for the ingredient is strictly as a release agent; (3) shows that the ingredient has always been used in their operations for the same purpose without labeling; (4) shows that the need to change the meat, poultry, or egg product labeling is only because their ingredient supplier's labeling has changed because of FALCPA provisions; and (5) obtains and maintains as part of the official labeling record a letter from the ingredient supplier stating that the formula of the ingredient mix has not changed, only the label needs to be modified because of FALCPA requirements. Any additional validation for the continued use of the labeling will also be considered. However, a prior history of no reported adverse reactions or the lack of recalls for the non-declaration of the ingredient is not sufficient to support the non-declaration of these ingredients. The manufacturer must modify the subject labels to include these ingredients at the next printing to replenish label stock, or when the labels are modified for other reasons.

4. **Question:** "Does a plant have to also declare on its labels that allergens are produced in their facility, and what they are as well?

Answer: Depending on the hazards identified by the establishment, there may be issues with the unintended presence of ingredients of public health concern. This is certainly one of the possibilities the establishment should consider. FSIS expects that in that case, SSOP or other prerequisite procedures would be implemented by the establishment to control this issue. In limited situations, the use of factual labeling statements about a product's manufacturing environment, e.g., "Produced in a plant that uses peanuts," may be used where good manufacturing practices, and effective SSOPs, cannot reasonably eliminate the unintended presence of certain ingredients. For further information, please refer to the following link to FSIS labeling policy on voluntary allergens statements:
http://www.fsis.usda.gov/regulations_&_policies/ingredients_guidance/index.asp

5. **Question:** "What is the definition of highly refined oil?"

Answer: Highly refined edible oils are the result of processing that involves de-gumming, neutralizing, bleaching, and deodorizing the oils extracted from plant-based starting materials, such as soybeans and peanuts. Refining improves the quality of plant oils by removing undesirable free fatty acids, gums, and phosphatides, imparting uniform color and eliminating undesired odors to make the product acceptable from the sensory perspective for human consumption. A benefit of refining edible oils is that the refining process renders them virtually free of allergenic protein according to information provided on the Institute of Shortening and Edible Oils website. According to the Institute of Shortening and Edible Oils, the vast preponderance of edible oils consumed in the U.S. are highly refined and processed to the extent that allergenic proteins are not present in detectable amounts. Scientific studies indicate that refined oils are safe for the food-allergic population to consume. In contrast, mechanical or "cold press" extraction of oils from plant materials may not remove all protein. However, cold-pressed oils are rarely used.

6. **Question**: "Is soy bean oil an allergen?"

Answer: Highly refined vegetable oils are not considered allergens according to allergens experts. Because the protein from the soybean is typically removed during the

refining of the oil, it is not considered an allergen.

7. **Question**: "Is fully hydrolyzed soy/wheat protein a source of allergen?"

Answer: It is not a matter of whether or not this ingredient is a source of an allergen. It is a matter of declaring these ingredients by common or usual name in labeling. As stated in the FSIS March 1995 policy guidance cited above, FDA has established a common or usual name for hydrolyzed (source) proteins, viz., hydrolyzed soy protein, hydrolyzed wheat gluten, regardless of the degree to which the proteins in such ingredients have been broken down. According to FDA, appropriate standards exist to allow distinction between commercially available "highly" hydrolyzed protein hydrolysates and those variously termed "partially," "mildly," or "lightly" hydrolyzed that are not used for flavor-related purposes.

According to FDA, "highly" hydrolyzed proteins are declared as "hydrolyzed (source) protein" and can be defined as those whose ratio of alpha-amino nitrogen (AN) to total nitrogen (TN) is greater than 0.62 (AN:TN>0.62). Proteins that are not highly hydrolyzed would have AN:TN of less than 0.62 (AN:TN<0.62) and may be termed "partially," "mildly," or "lightly," e.g., "partially hydrolyzed (source) protein."

8. **Question**: "What are all of the sensitive ingredients that are of concern? Where can I find a complete list of ingredients that may cause adverse reactions?

Answer: FSIS has not established a list of ingredients to which consumers have reported adverse reactions. The general rule is that, with few exceptions, all ingredients are expected to be declared on the labeling of meat, poultry, and egg products. FSIS guidance for many years has been that ingredients that are of health concern should always be declared, particularly those containing protein and those that are reported to be sources of intolerances in sensitive individuals. It is the responsibility of the establishment as part of their hazard analysis to research the ingredients they are using in the production of their products and determine whether the ingredients may trigger food sensitivities, and whether they have considered and employed the necessary in-plant controls to prevent cross-contact and assure accurate label declarations.